San Diego
Blood Bank
A Regional Blood Center

December 16, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 98N-0581: Requirements for Testing Human Blood for Evidence of Infection Due to Communicable Disease Agents

To Whom It May Concern:

This letter is to comment on the Food and Drug Administration's (FDA) notice regarding the draft guidance entitled "Requirements for Testing Human Blood for Evidence of Infection Due to Communicable Disease Agents" announced in the Federal Register of August 19, 1999.

San Diego Blood Bank supports the goal of FDA to assist blood establishments in protecting the safety of the blood supply and to establish policies with the intent of promoting consistency in the industry. We seek clarification and offer requested input in the following:

610.40(a)

We support maintaining flexibility by allowing testing to be completed only once at the beginning of a 30-day period of donation by a dedicated apheresis donor for a single recipient. Use of an abbreviated donor screening questionnaire would be helpful. Units should not be labeled as untested as the test results are not expected to change within the 30-day time frame.

610.40 (c)

This proposed regulation requires that all blood donations with a repeatably reactive test results be further tested with a more specific supplemental test. The SDBB disagrees with this requirement. For example, when a first time donor tests repeatable reactive for HCV, the donor is permanently deferred as there is no re-entry algorithm currently in place or approved by the FDA. To force a blood center to further test these donations for the presence of HCV, even though the outcome of deferring the donor will not change places an undo burden on the blood center. The blood center is placed into the role of health care provider inappropriately, when the

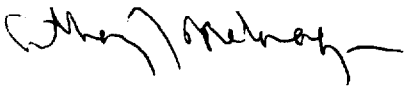
98N-0581 C22

donor should be seeking medical attention for his/her own physician. The SDBB supports voluntary confirmatory testing, but does not support required confirmatory testing.

The FDA asked for comments regarding the continued use of syphilis testing of blood donation. We support the elimination of testing for syphilis as a marker of high-risk behavior, as a surrogate test for other infectious diseases, and in preventing the transmission of syphilis through blood transfusion. It is well documented that STS positive donations reflect a non-specific test reactivity or a treated historical infection.

Thank-you for this opportunity to comment on FDA's draft "Requirements for Testing Human Blood for Evidence of Infection Due to Communicable Disease Agents". If you have any questions, please feel free to contact me or the Director of Quality Assurance/Compliance, Ms. Patricia E. Bakke, by phone at (619) 296-6393, or by e-mail at tmelaragno@bloodbank.org or pbakke@bloodbank.org.

Sincerely,



Anthony J. Melaragno, M.D.
Medical Director/CEO
San Diego Blood Bank

San Diego
Blood Bank
A Regional Blood Center
440 Upas Street
San Diego, California 92103-4900

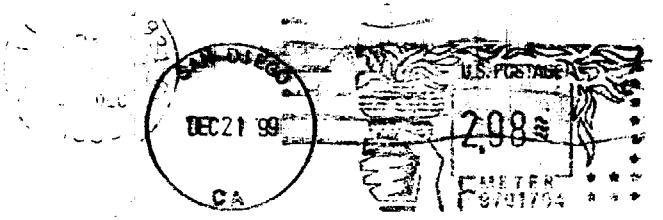
Fold at line over top of envelope to the right of the return address

CERTIFIED

Return Receipt Requested

Z 160 624 809

MAIL



Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

20857-0001